



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB review; 30-day Comment Request; PHS Applications and Pre-Award Related Reporting (Office of the Director)

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](https://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Mikia P. Currie, Program Analyst, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 803-B, Bethesda, Maryland 20892, or call non-toll-free number (301) 435-0941 or e-mail your request, including your address to:

[ProjectClearanceBranch@mail.nih.gov](mailto:ProjectClearanceBranch@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** This proposed information collection was previously published in the *Federal Register* on June 8, 2022, pages 34891/34892 (87 FR 34891) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The Office of the Director, Office of Extramural Research (OER), National Institutes of Health (NIH), may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, NIH has submitted to OMB a request for review and approval of the information collection listed below.

Proposed Collection: Public Health Service (PHS) Applications and Pre-Award Related Reporting - 0925-0001 – 09/30/2024, REVISION, Office of the Director, National Institutes of Health (NIH).

Need and Use of Information Collection: The National Institutes of Health (NIH) and other Public Health Service (PHS) agencies currently use the Research and Research Training Grant Applications and Related Forms and Ruth L. Kirschstein National Research Service Award Applications and Related Forms (0925-0001 Expiration Date: September 30, 2024). This collection is being revised to update competing application forms for the implementation of the final NIH Policy for Data Management and Sharing (DMS Policy) to promote the management and sharing of scientific data generated from NIH-funded or conducted research. Starting in January 2023, NIH will require applicants and recipients to submit and address Data Management and Sharing (DMS) Plans within the SF424 Research and Related (R&R) application and the Research Performance Progress Report (RPPR) in accordance with the DMS Policy. The application and progress report forms will be updated to align with this requirement. NIH is also introducing a new, optional DMS Plan format page that applicants may use to develop their DMS Plan. This collection is also being updated to include the application form for NIH Other Transaction awards. Post-award reporting requirements, including the RPPR, are similarly consolidated and concurrently submitted under 0925-0002 (expiration September 30, 2024).

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,175,670.

#### Estimated Annualized Burden Hours

Information Collection Forms	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
PHS 398 - Paper	4,247	1	35	148,645
PHS 398/424 - Electronic				
PHS Assignment Request Form	37,120	1	30/60	18,560
PHS 398 Cover Page Supplement	74,239	1	1	74,239
PHS 398 Modular Budget	56,693	1	1	56,693
PHS 398 Training Budget	1,122	1	2	2,244
PHS 398 Training Subaward Budget Attachment(s) Form	561	1	90/60	842
PHS 398 Research Plan	70,866	1	10	708,660
PHS 398 Research Training Program Plan	1,122	1	10	11,220
Data Tables	1,515	1	4	6,060
PHS 398 Career Development Award Supplemental Form	2,251	1	10	22,510
PHS Human Subjects and Clinical Trial Information	54,838	1	13	712,894
Biosketch (424 Electronic)	80,946	1	2	161,892
Data Management and Sharing Plan	73,117	1	2	146,234
PHS Fellowship - Electronic				
PHS Fellowship Supplemental Form (includes F reference letters)	6,707	1	13	87,191
Biosketch (Fellowship)	6,707	1	2	13,414
416-1	29	1	10	290
PHS 416-5	6,707	1	5/60	559
PHS 6031	6,217	1	5/60	518
VCOC Certification	6	1	5/60	1
SBIR/STTR Funding Agreement Certification	1,500	1	15/60	375
NIH Other Transaction				

NIH Other Transaction Application Form	239	1	11	2,629
<b>Total Annual Burden Hours</b>	-----	<b>486,749</b>	-----	<b>2,175,670</b>

**Dated:** September 27, 2022.

**Tara A. Schwetz,**

*Acting Principal Deputy Director,*

*National Institutes of Health.*

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